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No. 06-1249

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IN THE

Supreme Court of the United States

WYETH,

Petitioner,

v.

DIANA LEVINE,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE SUPREME COURT OF THE STATE OF VERMONT

SUPPLEMENTAL BRIEF FOR PETITIONER

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STATEMENT PURSUANT TO RULE 29.6

Petitioner's corporate disclosure statement was set forth at page *ii* of its Petition for a Writ of Certiorari, and there are no amendments to that statement.

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Wyeth filed a petition for writ of certiorari in the above-captioned case on March 12, 2007. *See* Petition for a Writ of Certiorari, *Wyeth v. Levine*, No. 06-1249 (U.S. Mar. 12, 2007) ("Pet."). On May 21, 2007, the Court requested the views of the United States. The United States responded on December 21, 2007 and agreed with Petitioner that Respondent's state-law claims are preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA") "because they challenge labeling that FDA approved, after being informed of the relevant health risk, based on its expert weighing of the risks and benefits of requiring additional or different warnings." Brief for the United States as Amicus Curiae at 7, *Wyeth v. Levine*, No. 06-1249 (U.S. Dec. 21, 2007) ("U.S. Br."). The United States also asked the Court to hold the petition pending disposition of *Riegel v. Medtronic, Inc.*, No. 06-179 (argued Dec. 4, 2007), and *Warner-Lambert Co., LLC v. Kent*, No. 06-1498, (cert. granted Sept. 25, 2007). Petitioner respectfully submits this supplemental brief to urge the Court to grant the petition and schedule the case for review this Term.

1. The United States expressed complete agreement with two critical legal arguments set forth in the petition. Specifically, the United States agreed with Petitioner that 21 C.F.R. § 314.70, FDA's "Changes Being Effected," or "CBE" regulation, does not allow drug manufacturers unilaterally to change FDA-approved labeling to strengthen a warning unless they acquire "material new information—not information that was previously available to FDA, nor even cumulative new information that does not add materially to the information that was previously available to the agency." U.S. Br. at 14. This construction of the CBE regulation, which the United

States agrees foreclosed Wyeth from modifying its Phenergan label as required by the Vermont Supreme Court, *id.*, is entitled to substantial judicial deference. *Auer v. Robbins*, 519 U.S. 452, 461 (1997). The United States also agreed with Petitioner that the "direct and positive" language of the Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780, § 202 ("Section 202"), reflects Congress' desire to preclude field preemption—not to limit conflict preemption analysis "to some subset of conflict preemption." U.S. Br. at 17 (citing *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 873 (2000)).

2. The United States also implicitly acknowledged that the question presented here satisfies the criteria for review set forth in this Court's Rule 10. As its brief explained, decisions such as that reached by the Vermont Supreme Court conflict with numerous decisions of this Court and, importantly, undermine FDA's "expert determination, based on a careful review of extensive scientific and technical information, that a drug is safe and effective when used according to its labeling, and that the labeling satisfies federal requirements." *Id.* at 9-10. "If [as held by the Vermont Supreme Court] manufacturers were free to make unilateral changes to labeling the day after FDA's approval, based on information that was previously available to FDA, the approval process would be greatly undermined and the agency's careful balancing of risks and benefits thwarted." *Id.* at 12.

3. The United States suggested that the petition should be held because the "decision below does not squarely conflict with any decision of a federal court of appeals or another state supreme court" and because "decisions in two pending FDA preemption cases"—the

Riegel and *Warner-Lambert* cases identified above—"may shed significant light on the question presented in this case." *Id.* at 7-8. Wyeth believes that, to the extent that there is some overlap with issues presented in *Riegel* and *Warner-Lambert*, the Court would benefit from the fuller development of those issues afforded by contemporaneous consideration of this case. Moreover, deciding this case promptly would greatly assist the many lower courts now facing conflict preemption issues in thousands of prescription drug product liability cases.

4. The United States argues that the decision below did not squarely conflict with the California Supreme Court's decision in *Dowhal v. Smithkline Beecham Consumer Healthcare*, 88 P.3d 1 (Cal. 2004), because the *Dowhal* court gave controlling deference to FDA's "specific prohibition of the warnings that would have complied with California law" rather than an FDA labeling decision. U.S. Br. at 19-20. The government speculated that "the Vermont Supreme Court might have found preemption in a case like *Dowhal* even under its erroneous impossibility standard of conflict preemption." *Id.* at 20. Whatever the Vermont Supreme Court might or might not be willing to do in a *Dowhal* situation, however, there remains a square conflict between the California Supreme Court's recognition that states cannot second guess the delicate benefit/risk balances struck by FDA on drug labeling issues and the Vermont Court's willingness to permit a lay jury to override FDA's judgment on the mistaken premise that the "FDCA and the FDA's regulations . . . merely set minimum standards." Pet. at 11a-12a (quoting *McNellis v. Pfizer, Inc.*, No. Civ. 05-1286 JBS, 2005 WL 3752269, at *7 (D.N.J. Dec. 29, 2005)) (internal quotations omitted).

5. A similar fundamental conflict has arisen between the decision below and the Third Circuit's recent decision preempting certain state law advertising claims relating to drug labels in *Pennsylvania Employees Benefit Trust Fund v. Zeneca, Inc.*, 499 F.3d 239, 251 (3d Cir. 2007) (preempting state-law claims because "the purpose of protecting prescription drug users in the FDCA would be frustrated if states were allowed to interpose consumer fraud laws that permitted plaintiffs to question the veracity of statements approved by the FDA"). The Third Circuit thus correctly recognized that the FDA's pervasive drug regulatory powers precluded second-guessing its considered scientific judgments. *Id.* at 251-52. This result led the plaintiffs to file a petition for a writ of certiorari in which they argued that the Third Circuit's preemption decision conflicts with the Vermont Supreme Court's rejection in *Levine* of any conflict between state law duties and "obligations under federal law regulating prescription drug labels." Petition for a Writ of Certiorari, *Penn. Employees Benefit Trust Fund v. Zeneca Inc.*, No. 07-822 (U.S. Dec. 18, 2007) (quoting Pet. at 2a) (internal quotations omitted) ("Penn. Pet.").[1]

6. Indisputably, a deep split in authority persists in the numerous lower court decisions cited in Wyeth's Petition, Pet. at 16 (collecting pre-*Levine* decisions supporting "minimum standards" view of FDCA), as well

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1. Other plaintiffs seeking recovery under state law also are relying on the case below in ongoing litigation. *See, e.g.*, Brief of Appellant, *Conte v. Wyeth*, No. A16707 (Cal. App. 3d Div. Sept. 21, 2007); Brief of Appellant, *McKenney v. Purepac Pharm. Co.*, No. F052606 (Cal. App. 5th Div. Oct. 9, 2007); Brief of Appellant, *Ledbetter v. Merck & Co.*, No. 14-07-00551-CV (Tex. App. 14th Dist. Oct. 17, 2007).

as in cases that have since been decided, *see, e.g.*, *In re Vioxx Prods. Liab. Litig.*, 501 F. Supp. 2d 776, 786 (E.D. La. 2007); *In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 275-77 (E.D.N.Y. 2007). Allowing more courts to reject the proper understanding of the FDCA put forward by Petitioner and the United States will only exacerbate an already troubling state of affairs in the lower courts. Although the United States' rejection of the "minimum standards" view of the FDCA and of the Vermont Supreme Court's misconstruction of the CBE regulation should be determinative, it gives little real assurance against continuing error in the vast majority of lower court cases. Pet. at 29 (collecting cases denying deference to FDA's interpretation of FDCA and its implementing regulations). Review by the Court during this Term would advance important interests of judicial economy and efficiency, for it will provide the lower courts with guidance on an important legal issue that is likely to affect thousands of pending cases.

7. Given the multiplicity and importance of prescription drug product liability cases, calendaring this case for argument so that it may be considered contemporaneously with *Riegel* and *Warner-Lambert* would enrich this Court's consideration of such potentially overlapping issues as the "floor and ceiling" characteristics of the Medical Device Amendments ("MDA") to FDCA and FDCA drug approval regimes, and their limitations on post-approval labeling changes.[2]

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2. While the United States noted that *Warner-Lambert* "involves implied preemption of claims involving FDA's approval of a new drug application," U.S. Br. at 22, the principal focus of that case is whether state statutory immunity from tort liability

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Simultaneous review will allow the Court to consider fully whether there is any meaningful difference between MDA statutory preemption and conflict preemption under FDCA, a question that repeatedly arose during the *Riegel* oral argument. Oral Argument Transcript at 8-12, 25, 44, *Riegel v. Medtronic, Inc.*, No. 06-179 (U.S. Dec. 4, 2007). Indeed, given the routine and mistaken failure of a number of lower courts to apply clearly analogous MDA precedent in resolving FDCA preemption issues, it is essential that the Court speak directly to FDCA preemption as well as MDA preemption. *See, e.g., In re Vioxx Prods. Liab. Litig.*, 501 F. Supp. 2d at 784; *Caraker v. Sandoz Pharms. Corp.*, 172 F. Supp. 2d 1018, 1041-42 (S.D. Ill. 2001); *Cartwright v. Pfizer, Inc.*, 369 F. Supp. 2d 876, 885 (E.D. Tex. 2005).

8. Moreover, the applicability and meaning of Section 202, which was central to the Vermont Supreme Court's truncated preemption analysis here, is not presented in *Riegel*. Only this Court's authoritative construction of Section 202 and the CBE regulation will provide the necessary, definitive guidance in the thousands of drug labeling cases pending in the lower courts. *See, e.g.*, Penn. Pet. at 32 (arguing that the "phrase 'direct and positive conflict' demonstrates that Congress intended *not* to pre-empt state-law claims").

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for prescription drugs labeled in accordance with FDA approval can include an exclusion for fraud on FDA, a dispute that turns on the meaning of this Court's decision in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). Thus, as the United States recognized, *Warner-Lambert* is unlikely to resolve the question presented here.

9. At base, the United States has advanced a powerful, and indeed unassailable, paradigm for FDA preemption that necessitates reversal here: "Because respondent's claims challenge labeling that FDA approved after being informed of the relevant risk, they conflict with FDA's approval of the labeling and are therefore preempted." U.S. Br. at 8. This view of the FDCA and FDA's implementing regulations, however, has met stiff resistance in the lower courts. This Court should grant the petition and schedule the case for review this Term to properly conclude this longstanding debate.

CONCLUSION

For the foregoing reasons, Petitioner respectfully requests that the Court grant the petition for a writ of certiorari.

Respectfully submitted,

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